

the questionnaire in each country, and comparability of data across countries.

PKU4

LINGUISTIC VALIDATION OF THE KING'S HEALTH QUESTIONNAIRE (KHQ) IN EIGHT LANGUAGES

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OBJECTIVES: While measurement of quality of life (QoL) has become a vital part of assessing urinary incontinence in women, linguistically validated language versions of a measure including questions on QoL, strategies for coping and the severity of symptoms has not been available. Prior to use in an international trial, the King's Health Questionnaire (KHQ) designed in UK English had to undergo cross-cultural adaptation in eight languages.

METHODS: The translation process of the KHQ, coordinated by a QoL specialist in each target country, employed the following methodology: 1) two forward translations by professional translators, native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by QoL specialist and translators; 3) backward translation by a native English speaker; 4) comparison of source and backward version; 5) comprehension test in a sample target population; 6) international harmonization.

RESULTS: Linguistic and conceptual issues emerged when translating idiomatic English phrases and the original response scales. No linguistic equivalent was available for idiomatic expressions such as "waterworks infection" or "make you feel bad about yourself" and the term "bladder" was revealed as being too technical during comprehension tests. Patient testing also showed that a response option "not applicable" was lacking for certain questions. To harmonize with the validated original however, no changes were made in the response categories.

CONCLUSIONS: A rigorous translation methodology was performed to ensure conceptual equivalence and cross-cultural acceptability of translations. Psychometric testing will be conducted to ensure reliability and validity in each translation. This work highlights the value of integrating international feedback into instrument design.

PKU5

ACUTE REJECTION EPISODES ARE ASSOCIATED WITH HIGHER UTILIZATION OF RESOURCES AFTER KIDNEY TRANSPLANTATION

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Sirolimus (rapamycin), in combination with standard immunosuppressive therapy, significantly reduced the incidence of acute rejection (AR) in a prospective trial in kidney transplant recipients. The purpose of this study was to determine the relationship between resource utilization and the number of AR episodes.

METHODS: Medical resource utilization data were collected for 719 US patients enrolled in a randomized, double-blind, controlled clinical trial. Patients were categorized into three groups according to their experience of AR (both biopsy confirmed and presumptive) during the first 6 months post transplant: those who had no AR (N = 542), one AR episode (N = 125), and two or more AR episodes (N = 52). Measures of medical resource utilization were compared between groups. The measures included mean hospital days, days on dialysis, and amount of concomitant immunosuppressive rescue medications. Different immunosuppressive rescue drugs were combined into a single measure in the analysis using cost estimates based on average wholesale prices.

RESULTS: Patients experiencing one AR episode had higher resource utilization rates (18.8 hospital days, 10.6 days on dialysis, and \$10,600 cost of concomitant immunosuppressive rescue drugs) compared with those experiencing none (12.6 hospital days, 1.7 days on dialysis, and \$1400 of rescue drugs). Patients with multiple AR episodes had the highest rates of resource utilization (20.5 days of hospitalization, 10.4 days on dialysis, and \$16,600 of concomitant immunosuppressive rescue drugs). All three-way differences were significant at the .05 level based on F-tests.

CONCLUSIONS: AR episodes in kidney transplant patients were associated with higher utilization of resources during the first six months post-transplantation. A reduction in the AR rate by sirolimus may offer both improved economic as well as clinical outcomes.

PKU6

COST-EFFECTIVENESS ANALYSIS OF MYCOPHENOLATE MOFETIL TREATMENT FOR INTRACTABLE ACUTE REJECTION IN RENAL TRANSPLANTATION RECIPIENTS

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OBJECTIVE: A cost-effectiveness analysis comparison of mycophenolate mofetil, a new immunosuppressant, and muromonab CD3 in patients with intractable acute rejection after renal transplantation was conducted.

METHODS: A clinical decision analytic model was created based upon their use in Nagoya Second Red Cross Hospital. This study was analyzed from the payer's perspective. The cost data were obtained from the center based on what would be paid to the hospital according to the Health Insurance Price of April 1996. The survival of the graft at 90 days was used as an effectiveness endpoint